UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, *et al.*, Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LIMITED, *et al.*, Defendants.	Civil Action No. 20-5426 (SRC) (CLW) (CONSOLIDATED) *Document Electronically Filed* **STIPULATION AND ORDER REGARDING LIMITATION OF CLAIMS AND DEFENSES**

WHEREAS Plaintiffs Bausch Health Ireland Limited, Bausch Health Americas Inc., and Bausch Health US, LLC (collectively, "Bausch" or "Plaintiffs"), and Defendants Padagis Israel Pharmaceuticals Limited and Padagis US LLC (collectively, "Padagis" or "Defendants") seek to reduce the scope of the consolidated above-captioned case (the "Action") in order to conserve their and the Court's resources;

NOW THEREFORE, Plaintiffs and Defendants, subject to the Court's approval, hereby stipulate and agree as follows:

1. Padagis Israel Pharmaceuticals Limited has submitted Abbreviated New Drug Application No. 214285 ("Padagis's Halobetasol ANDA") seeking approval to market a generic halobetasol topical lotion, 0.01% ("Padagis's Halobetasol ANDA Product").

2. Padagis Israel Pharmaceuticals Limited has submitted Abbreviated New Drug Application No. 214626 ("Padagis's Halobetasol and Tazarotene ANDA") seeking approval to market a generic halobetasol and tazarotene topical lotion, 0.01%/0.045% ("Padagis's Halobetasol and Tazarotene ANDA Product").

3. Plaintiffs assert in this Action that Defendants infringed certain claims[1] of U.S. Patent Nos. 8,809,307 and 10,478,502 under 35 U.S.C. § 271(e)(2) by submitting Padagis's Halobetasol ANDA and would also infringe the same claims (directly or indirectly) under 35 U.S.C. § 271(a)-(c) by making, using, offering to sell, or selling Padagis's Halobetasol ANDA Product.

4. Plaintiffs assert in this Action that Defendants infringed certain claims[2] of U.S. Patent Nos. 8,809,307, 10,478,502, 10,251,895, and 10,426,787 under 35 U.S.C. § 271(e)(2) by submitting Padagis's Halobetasol and Tazarotene ANDA and would also infringe the same claims (directly or indirectly) under 35 U.S.C. § 271(a)-(c) by making, using, offering to sell, or selling Padagis's Halobetasol and Tazarotene ANDA Product.

5. Plaintiffs agree not to assert any claims at trial in this Action, other than the following: claims 13, 16, and 20 of U.S. Patent No. 8,809,307; claims 4 and 16 of U.S. Patent No. 10,478,502; claims 3 and 6 of U.S. Patent No. 10,251,895; and claims 4, 5, and 7 of U.S. Patent No. 10,426,787 (collectively, the "Asserted Claims").

6. Without prejudice to Padagis's positions regarding the invalidity of the Asserted Claims, Padagis stipulates that the submission of Padagis's Halobetasol ANDA to the FDA infringed each of the Asserted Claims of U.S. Patent Nos. 8,809,307 and 10,478,502.

7. Without prejudice to Padagis's positions regarding the invalidity of the Asserted Claims, Padagis stipulates that the manufacture, use, offer to sell, sale, and/or importation of Padagis's Halobetasol ANDA Product would infringe each of the Asserted Claims of U.S. Patent Nos. 8,809,307 and 10,478,502.

---

[1] With respect to Padagis's Halobetasol ANDA Product, Plaintiffs have asserted claims 1-5, 7, 12-17, 19-20, 22-23, and 28 of U.S. Patent Nos. 8,809,307 and claims 1-6 and 8-16 of U.S. Patent No. 10,478,502.

[2] With respect to Padagis's Halobetasol and Tazarotene ANDA Product, Plaintiffs have asserted claims 1-4, 7, 12-13, 15-17, 19, and 20 of U.S. Patent Nos. 8,809,307; claims 1-5 and 8-16 of U.S. Patent No. 10,478,502; claims 1-3, 5, and 6 of U.S. Patent No. 10,251,895; and claims 1-5 and 7 of U.S. Patent No. 10,426,787.

8. Without prejudice to Padagis's positions regarding the invalidity of the Asserted Claims, Padagis stipulates that the submission of Padagis's Halobetasol and Tazarotene ANDA to the FDA infringed each of the Asserted Claims of U.S. Patent Nos. 8,809,307 and 10,478,502.

9. Without prejudice to Padagis's positions regarding the invalidity of the Asserted Claims, Padagis stipulates that the manufacture, use, offer to sell, sale, and/or importation of Padagis's Halobetasol and Tazarotene ANDA Product would infringe each of the Asserted Claims of U.S. Patent Nos. 8,809,307 and 10,478,502.

10. Without prejudice to Padagis's positions regarding the invalidity of the Asserted Claims, Padagis stipulates that Padagis's Halobetasol and Tazarotene ANDA Product satisfies each limitation of the Asserted Claims of U.S. Patent No. 10,251,895 and U.S. Patent No. 10,426,787, except for the Synergism Limitations.[3]

11. Bausch agrees that it will not seek fact depositions of Padagis, Padagis's employees, or Padagis's former employees during the remainder of the litigation. Bausch agrees to withdraw Bausch's Notice of Rule 30(b)(6) Deposition to Padagis, Bausch's First Supplemental Notice of Rule 30(b)(6) Deposition to Padagis, and the individual deposition notices to Amira Zeevi, Chaim Aschkenasy, Dalit Fuchs, Matthew Cronin, and Richard Stec.[4]

12. Padagis agrees that, by January 28, 2022, it will provide Plaintiffs with a disclosure of the references which Padagis will collectively rely upon, that Padagis contends render the Asserted Claims obvious under 35 U.S.C. § 103 (the "§ 103 Disclosure"). The references in the § 103 Disclosure must already have been disclosed in Padagis's invalidity contentions. Padagis agrees that its trial presentation of combinations of references that render

[3] "Synergism Limitations" refers to the limitations in independent claim 1 of each of U.S. Patent Nos. 10,251,895 and 10,426,787, which recite: "wherein the composition comprising the halobetasol propionate and the tazarotene at said concentrations is capable of providing synergistic efficacy and synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging[.]"

[4] Notwithstanding the foregoing paragraph, the parties have agreed to defer the issue of whether Bausch will continue to seek deposition testimony in response to Topic Nos. 62, 63, and 71 in Bausch's Notice of Rule 30(b)(6) Deposition to Padagis.

the Asserted Claims invalid under 35 U.S.C. § 103 will be limited to the references included in the § 103 Disclosure. Padagis reserves the right to rely upon references outside the scope of the § 103 Disclosure for background information, including to establish the knowledge of a skilled artisan and a skilled artisan's motivation to modify and/or combine the references identified in the § 103 Disclosure, and to rebut any invalidity arguments and/or secondary considerations arguments raised by Plaintiffs. Padagis agrees, however, that the prior art that forms the basis of its invalidity claims under 35 U.S.C. § 103 will be limited to the references identified in the § 103 Disclosure.

13. Padagis agrees that the § 103 Disclosure will include no more than 20 discrete prior art references.[5,6] Padagis agrees to limit its expert reports to no more than 15 combinations and trial presentation to no more than 10 combinations of the references in the § 103 Disclosure.

14. Padagis agrees that HALOBET0000001–HALOBET0015748 is an authentic and genuine copy of Padagis's Halobetasol ANDA, as well as correspondence from the FDA regarding Padagis's Halobetasol ANDA.

15. Padagis agrees that HALOBET0015301-HALOBET0015309 is an authentic and genuine copy of Padagis's proposed label for Padagis's Halobetasol ANDA Product.

16. Padagis agrees that HAL-TAZ0000001–HAL-TAZ0015013, HAL-TAZ0015022–HAL-TAZ0015028 is an authentic and genuine copy of Padagis's Halobetasol and Tazarotene ANDA, as well as correspondence from the FDA regarding Padagis's Halobetasol ANDA.

17. Padagis agrees that HAL-TAZ0000155–HAL-TAZ0000157 is an authentic and genuine copy of Padagis's proposed label for Padagis's Halobetasol and Tazarotene ANDA Product.

---

[5] A reference constitutes a "prior art reference" if Defendants contend that the reference is prior art, regardless of whether Plaintiffs contend otherwise and whether the Court concludes otherwise.

[6] The limits in this paragraph apply to the Asserted Claims collectively, not on a claim by claim basis.

18. Padagis agrees to further stipulate to the authenticity, in the same manner as set forth in ¶¶ 14-17 above, of any documents submitted to the FDA in support of its Halobetasol ANDA and of its Halobetasol and Tazarotene ANDA, which (i) have not yet been produced to Bausch but (ii) are produced to Bausch after the date of this stipulation.

19. Padagis agrees to further stipulate to the authenticity, in the same manner as set forth in ¶¶ 14–17 above, of any correspondence between Padagis and the FDA in connection with Padagis's Halobetasol ANDA and its Halobetasol and Tazarotene ANDA, which (i) has not yet been produced to Bausch but (ii) is produced to Bausch after the date of this stipulation.

SO STIPULATED:

Dated: December 22, 2021

s/ William P. Deni, Jr.
William P. Deni, Jr.
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com
jlower@gibbonslaw.com

Thomas P. Steindler (*pro hac vice*)
April E. Weisbruch (*pro hac vice*)
David Mlaver (*pro hac vice*)
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street N.W.
Washington, D.C. 20001
(202) 756-8000

Attorneys for Plaintiffs
Bausch Health Ireland Limited,
Bausch Health Americas Inc.,
and Bausch Health US, LLC

Dated: December 22, 2021

s/ Karen A. Confoy
Karen A. Confoy
Cali R. Spota
FOX ROTHSCHILD LLP
Princeton Pike Corporate Center
997 Lenox Drive
Lawrenceville, New Jersey 08648
Tel: (609) 896-3600
Fax: (609) 896-1469
kconfoy@foxrothschild.com
cspota@foxrothschild.com

Joseph M. Reisman (p*ro hac vice*)
KNOBBE, MARTENS, OLSON & BEAR, LLP
12790 El Camino Real
San Diego, CA 92130
(858) 707-4000

Bill Zimmerman (p*ro hac vice*)
Cassie Gourash (p*ro hac vice*)
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue N.W.
Suite 900
Washington D.C. 20006
(202) 640-6400

Carol Pitzel Cruz (p*ro hac vice*)
KNOBBE, MARTENS, OLSON & BEAR, LLP
925 Fourth Avenue, Suite 2500
Seattle, WA 98104
(206) 405-2000

Attorneys for Defendants Padagis Israel Pharmaceuticals Limited and Padagis US LLC

SO ORDERED this 23rd day of December, 2021:

s/ Stanley R. Chesler

Hon. Stanley R. Chesler, U.S.D.J.